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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,217	05/06/2002	Peter Francis Leadley	0380-P02746US0	9951

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DANN, DORFMAN, HERRELL & SKILLMAN
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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,217

Applicant(s)

LEADLEY ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In a preliminary amendment, Claims 1, 8-15, 17-23, 26, 29, 33, 35, 37, 38, and 42 were amended and Claims 46-47 were added. Thus, Claims 1-47 are pending in the instant application.

Restriction

2. Restriction is required under 35 U.S.C. § 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R. § 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group 1, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding GdhA and related products.
- Group 2, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding DapA and related products.
- Group 3, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding OFR3 and related products.
- Group 4, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding KsX and related products.
- Group 5, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonCII and related products.
- Group 6, claim(s) 1-3, 6, 8-12, 46-47, drawn to DNA encoding MonE and related products.
- Group 7, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonT and related products.
- Group 8, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonRII and related products.
- Group 9, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonAIX and related products.
- Group 10, claim(s) 1-3, 6-12, 30-34, 37-38, 46-47, drawn to DNA encoding MonAI and related products.
- Group 11, claim(s) 1-3, 6-12, 30-34, 37-38, 46-47, drawn to DNA encoding MonAII and related products.
- Group 12, claim(s) 1-3, 6-12, 30-34, 37-38, 46-47, drawn to DNA encoding MonAIII and related products.
- Group 13, claim(s) 1-3, 6-12, 30-34, 37-38, 46-47, drawn to DNA encoding MonAIV and related products.
- Group 14, claim(s) 1-3, 6-12, 30-34, 37-38, 46-47, drawn to DNA encoding MonAV and related products.
- Group 15, claim(s) 1-3, 6-12, 30-34, 37-38, 46-47, drawn to DNA encoding MonAVI and related products.

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- Group 16, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonH and related products.
- Group 17, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonCI and related products.
- Group 18, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonBII and related products.
- Group 19, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonBI and related products.
- Group 20, claim(s) 1-3, 6-12, 30-34, 37-38, 46-47, drawn to DNA encoding MonAVIII and related products.
- Group 21, claim(s) 1-3, 6-12, 30-34, 37-38, 46-47, drawn to DNA encoding MonAVII and related products.
- Group 22, claim(s) 1-3, 6, 8-12, 46-47, drawn to DNA encoding MonD and related products.
- Group 23, claim(s) 1-6, 8-12, 16, 41, 46-47, drawn to DNA encoding MonRI and related products.
- Group 24, claim(s) 1-6, 8-12, 16, 46-47, drawn to DNA encoding MonAX and related products.
- Group 25, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding ORF29 and related products.
- Group 26, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding LipB and related products.
- Group 27, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding ORF31 and related products.
- Group 28, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding ORF32 and related products.
- Group 29, claim(s) 1-3, 8-12, 46-47, drawn to DNA encoding AmtA and related products.

Groups 30-58, claim(s) 13-14, 18, drawn to methods of detecting PKS genes using any of the DNA of Groups 1-29, respectively (include Claim 15 for monAI and monRI) (include Claim 17 for those genes in Claim 16) (include Claim 19 for monH, monRI, monRII, monT monAI, and monAX)

- Group 59, claim(s) 21, drawn to methods of making a polyketide using monAIX.
- Group 60, claim(s) 21, drawn to methods of making a polyketide using monAX.
- Group 61, claim(s) 22, drawn to methods of synthesizing a polyketide using monBI.
- Group 62, claim(s) 22, drawn to methods of synthesizing a polyketide using monBII.
- Group 63, claim(s) 26, drawn to methods of synthesizing a polyketide using monCI.
- Group 64, claim(s) 26, drawn to methods of synthesizing a polyketide using monCII.
- Group 65, claim(s) 27, 29, drawn to methods of synthesizing a polyketide using a KS domain from monAI.
- Group 66, claim(s) 27, 29, drawn to methods of synthesizing a polyketide using a KS domain from monAII.
- Group 67, claim(s) 27, 29, drawn to methods of synthesizing a polyketide using a KS domain from monAIII.
- Group 68, claim(s) 27-29, drawn to methods of synthesizing a polyketide using a KS domain from monAIV.
- Group 69, claim(s) 27, 29, drawn to methods of synthesizing a polyketide using a KS domain from monAV.
- Group 70, claim(s) 27, 29, drawn to methods of synthesizing a polyketide using a KS domain from monAVI.
- Group 71, claim(s) 27, 29, drawn to methods of synthesizing a polyketide using a KS domain from monAVIII.

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Group 72, claim(s) 27, 29, drawn to methods of synthesizing a polyketide using a KS domain from monAVII.

Group 73, claim(s) 39-40, 42, drawn to methods of synthesizing a polyketide by overexpressing monRI.

Group 74, claim(s) 23, drawn to a polypeptide encoded by monBI.

Group 75, claim(s) 23, drawn to a polypeptide encoded by monBII.

Group 76, claim(s) 23, drawn to a polypeptide encoded by monAIX.

Group 77, claim(s) 23, drawn to a polypeptide encoded by monAX.

Group 78, claim(s) 24, drawn to a polypeptide encoded by monCI.

Group 79, claim(s) 25, drawn to a polypeptide encoded by monCII.

Group 80, claim(s) 35, drawn to a polyketide synthase polypeptide comprising a portion of the polypeptide encoded by monAI.

Group 81, claim(s) 35, drawn to a polyketide synthase polypeptide comprising a portion of the polypeptide encoded by monAII.

Group 82, claim(s) 35, drawn to a polyketide synthase polypeptide comprising a portion of the polypeptide encoded by monAIII.

Group 83, claim(s) 35, drawn to a polyketide synthase polypeptide comprising a portion of the polypeptide encoded by monAIV.

Group 84, claim(s) 35, drawn to a polyketide synthase polypeptide comprising a portion of the polypeptide encoded by monAV.

Group 85, claim(s) 35, drawn to a polyketide synthase polypeptide comprising a portion of the polypeptide encoded by monAVI.

Group 86, claim(s) 35, drawn to a polyketide synthase polypeptide comprising a portion of the polypeptide encoded by monAVIII.

Group 87, claim(s) 35, drawn to a polyketide synthase polypeptide comprising a portion of the polypeptide encoded by monAVII.

Group 88, claim(s) 20, 43-44, drawn to methods of expressing a heterologous gene in *S. cinnamonensis* using monRI.

Group 89, claim(s) 43-44, drawn to methods of expressing a heterologous gene in *S. cinnamonensis* using actII/orf4.

Group 90, claim(s) 36, drawn to a polyketides.

Group 91, claim(s) 45, drawn to 13-propyl erythromycin A.

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3. The inventions listed as Groups 1-92 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the first technical feature in Claim 1 is any DNA sequence encoding GdhA (or a sequence at least 80% identical to GdhA), the first peptide set out in Table II. This technical feature is not shared by any of the other DNA Groups 1-29 since each of these Groups are drawn to DNA encoding distinct proteins with different structures and different functions.

Moreover, this technical feature of Group I is not a special technical feature because the breadth of Claim 1 reads on *any* DNA sequence encoding even a single amino acid of the GdhA peptide ("at least a part of the sequence set out in the appended sequence listing"). Since no special technical feature is found in Group 1, no special technical feature can be shared with Groups 2-92.

Notice of Possible Rejoinder

4. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper

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restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues.

See M.P.E.P. § 804.01.

Election

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

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Examiner's Comments

6. The Examiner notes numerous typographical errors in Table I in the gene names with respect to their names in Table II.

Conclusion

7. A complete reply to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Examiner
Art Unit 1652

April 1, 2004